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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/623,887   | 07/17/2003  | Ulrich Posanski      | 4-20017E            | 7665             |
| 1095<br>NOVARTIS<br>CORPORATE INTELLECTUAL PROPERTY<br>ONE HEALTH PLAZA 104/3<br>EAST HANOVER, NJ 07936-1080 |             |                      |                     |                  |
| EXAMINER   |             |                      |                     |                  |
| ROBERTS, LEZAH   |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1612   |             |                      |                     |                  |
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| 04/14/2009   |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/623,887

**Applicant(s)**

POSANSKI, ULRICH

**Examiner**

LEZAH W. ROBERTS

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-893)  
Paper No(s)/Mail Date 27 Feb 2009
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

Applicants' arguments, filed November 28, 2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. This action is made NON-FINAL.

### *Claims*

#### **Claim Rejections - 35 USC § 112 – New Matter (New Rejection)**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite "consisting essentially of". The language does not appear to be disclosed and recited in the originally filed

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disclosure and claims. Therefore the transitional language "consisting essentially of" is "New Matter".

**Claim Rejections - 35 USC § 102 – Anticipation (New Rejection)**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11, 12, 14 and 16-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Uomoto et al. (US 5,380,745).

Uomoto et al. disclose medicinal compositions comprising a practically water-insoluble compound. The compositions may comprise either one or more compounds selected from either or both nonionic surfactants and fats and oils (Abstract). Surfactants include sorbitan fatty acid esters, polyoxyethylene sorbitan fatty acid esters and polyglycerol fatty acid esters (col. 2, lines 48-61). Oils include soybean oil, rapeseed oil, castor oil and cotton seed oil (col. 2, lines 62-66). Example 9 discloses a mixture comprising 20 g (40%) soybean oil, 12.5 g (25%) of polyoxyethylene (20) monostearate, 12.5 g (25%) of sorbitan monooleate and 2 g (4%) of the active agent.

The example encompasses the instant claims. The compositions may be incorporated into capsules (see Example 3).

**Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)**

Claims 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akiyama et al. (US 5,576,025) in view of Uomoto et al. (US 5,380,745)..

Akiyama et al. disclose compositions comprising a polyglycerol fatty acid and/or a lipid and an active agent (Abstract). Such composition can adhere to the digestive tract and remain there for a prolonged period of time, thereby increasing the bioavailability of the active ingredient. The amount of polyglycerol fatty acids in the matrix ranges 0.001 to 10,000 parts by weight of the active agent. The amount of lipid in the matrix ranges from 0.01 to 100 parts by weight of the active agent (col. 9, lines 51-67). Lipids include cottonseed oil and soybean oil. The amount of active in the matrix ranges from 0.0001 to 95% and includes ibuprofen col. 6, line 8). Surfactants may be used in the compositions and include polyoxyethylene-sorbitan fatty acid esters and sodium alkyl sulfates (col. 10, lines 20-23).

The reference differs from the instant claims insofar as it does not disclose amount of surfactant that may be used in the compositions.

Uomoto et al. is taught above and is used to disclose amounts of surfactants that may be used when delivering poorly soluble drugs. The compositions elevate water-solubility of the active compound and thus enhance the effect (Abstract). The nonionic surfactant may comprise 5 to 50 parts by weight of the active compound.

The reference differs from claims 13 and 15 insofar as it does not disclose the drugs of claim 13 and the specific polyglycerol fatty acid esters of claim 15.

Polyglycerol fatty acid and lipids may be used in combination with a nonionic surfactant. The amounts as disclosed by the combination of references range from 0.001 to 10,000 parts by weight, from 0.01 to 100 parts by weight and 5 to 50 parts by weight of the active agent, respectively. These amounts read on a 1:1:1:1, polyglycerol fatty acid, lipid, nonionic surfactant, and active agent, and are encompassed by the instant claims. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). The amounts as recited in the instant claims are obvious in view of the amounts disclosed by the combination of references disclosing the amount of polyglycerol fatty acid, lipid (oil) and a nonionic surfactant such as one having a HLB above 10 such as polyoxyethylene-sorbitan fatty acid esters consistent with In re Peterson.

It would have been obvious to one of ordinary skill in the art to one ordinary skill in the art to have incorporated a surfactant into the compositions of Akiyama et al. in the amounts disclosed by Uomoto et al. motivated by the desire to use an amount suitable for use with a poorly water soluble active.

Claim 15, which recites specific polyglycerols such as polyglyceryl-3-monooleate, is encompassed by the disclosure of oleyl glycerides such as oleyl mono(hexa)glyceride (col. 4, lines 51-55) as disclosed by Akiyama et al.

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It would also have been obvious to one of ordinary skill in the art to have used the compositions of Uomoto et al. to deliver the poorly soluble compounds of Akiyama et al. motivated by the desire to elevate water-solubility of the active compound and thus enhance the effect as disclosed by Uomoto et al.

Claims 11-22 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612